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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,840	10/31/2003	Timothy D. Gryseels	PC25024A	1267
28523	7590	11/01/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,840

Applicant(s)

GRYSEELS ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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This Application was filed October 31, 2003. The Applicants claim priority to U.S. Provisional Application 60/422,834, which was filed October 31, 2002.

Claims 1-20 are pending.

Election/Restrictions

Applicant's election of Invention I (claims 1-5) in the reply filed on September 27, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-20 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 24, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Doetschman et al. (1985, J. Embryol. Exp. Morph., 87:27-45; IDS reference).

Claims 1-4 are to a method of forming embryoid bodies comprising a culture vessel is inoculated with a culture of undifferentiated embryonic stem cells, wherein the culture vessel contains medium suitable for inducing embryoid body formation and wherein the culture vessel is subjected to shaking. The claims are directed to embryonic stem cells wherein the cells are of mammalian origin (claim 3), and more specifically, are of murine origin (claim 4).

Doetschman et al. teach that after mouse ES cells were established on feeder cell layers (page 29, "Establishment and maintenance of cell lines," lines 13-14), they were then cultured in the absence of embryonic fibroblasts in standard medium in either tissue culture dishes or in suspension in bacterial dishes or bottles placed on a rotary shaker (page 29, "Cell culture under differentiation conditions," lines 1-3). Suspension culture on a rotary shaker was shaken at 70 r.p.m. (page 29, "Cell culture under differentiation conditions," lines 8-9). Doetschman et al. teach that they identified differentiating cells cultured in standard medium without the addition of factors or inducers of any kind. Most of the cells formed aggregates and if the aggregates attached to the substrate, the cells that proliferated out from them differentiated into a variety of structures including glandular, heart, skeletal and smooth muscle, cartilage, nerve cells, keratin sworls, melanocytes, and embryoid bodies. Particularly for aggregates that were maintained in suspension, they developed only into embryoid bodies (page 33, "*In vitro* cultures," to page 34, first paragraph).

Claims 1, 3, 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Thomson et al. (U.S. Patent No 6,602,711 B1, issued August 5, 2003).

Claims 1, 3, 5 are to a method of forming embryoid bodies comprising a culture vessel which is inoculated with a culture of undifferentiated embryonic stem cells, wherein the culture vessel contains medium suitable for inducing embryoid body formation and wherein the culture vessel is subjected to shaking. The claims are directed to embryonic stem cells wherein the cells are of mammalian origin (claim 3), and more specifically, are of human origin (claim 5).

Thomson et al. anticipate claims 1, 3, 5. Thomson et al. teach that primate embryonic stem cells are initially cultured on mitotically inactivated mouse embryonic fibroblasts on tissue culture plastic with 0.1% gelatin (column 3, lines 48-53). Colonies are allowed to form clumps over a period of hours (column 3, lines 61-62) and are then removed from the culture plate enzymatically or mechanically. The ES cells are then put into suspension for further embryoid body formation. The cells are rocked continuously while suspended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson et al. in view of Doetschman et al.

Claims 1-3, 5 are to a method of forming embryoid bodies comprising a culture vessel which is inoculated with a culture of undifferentiated embryonic stem cells, wherein the culture vessel contains medium suitable for inducing embryoid body formation and wherein the culture vessel is subjected to shaking. The claims are directed to embryonic stem cells wherein the cells are of mammalian origin (claim 3), and more specifically, are of human origin (claim 5). While Thomson et al. teach that ES cells are put into suspension for further embryoid formation and are rocked continuously while suspended, they do not teach the speed at which the embryoid bodies should be rocked (claim 2).

Doetschman et al. teach in their Material and Methods section that mouse ES cells which were put in a suspension culture on a rotary shaker were shaken at 70 r.p.m. (page 29, "Cell culture under differentiation conditions," lines 8-9). ES cells then were allowed to form aggregates. ES cells that adhered to a substrate differentiated into various organ tissues. However, aggregates that were maintained in suspension, only developed into embryoid bodies (page 33, "*In vitro* cultures," to page 34, first paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the specific conditions for culturing

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mouse ES cells detailed by Doetschman et al. for culturing human ES cells into embryoid bodies as taught generally by Thomson et al.

One having ordinary skill in the art would have been motivated to substitute these cells, one for the other, in order to obtain human embryoid bodies (page 33, "*In vitro* cultures," to page 34, first paragraph).

There would have been a reasonable expectation of success given the results of Doetschman et al. demonstrating that unattached aggregates of ES cells would only form embryoid bodies and that Thomson et al. was producing human EB cells by keeping the cells in suspension via rocking.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

Joe Wontad

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